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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
SKOWRONEK, KARLHEINZ R	
ART UNIT	PAPER NUMBER
1631	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/763,567	GILMANSHIN ET AL.	
	Examiner	Art Unit	
	Karlheinz R. Skowronek	1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *14 February 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-4 and 6-54* is/are pending in the application.

4a) Of the above claim(s) *13,19,20,22,37 and 47-49* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-4,6-12,14-18,21,23-36,38-46 and 50-54* is/are rejected.

7)☒ Claim(s) *25,27,29-36,38,40-43 and 54* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *01-23-2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Status

Claims 1-4 and 6-54 are pending.

Claim 5 is cancelled.

Claims 13,19, 20, 22, 37, and 47-49 stand withdrawn as being directed to a non-elected invention.

Claims 1-4, 6-12,14-18, 21, 23-36, 38-48 and 50-54 are being examined.

Specification

Applicant's arguments, see p. 11, paragraph 2 of remarks, filed 14 February 2007, with respect to use of trademarks have been fully considered and are persuasive. The objection of the specification has been withdrawn.

Claim Rejections - 35 USC § 101

Applicant's arguments, see p. 11, paragraph 4-5 of remarks, filed 14 February 2007, with respect to non-statutory subject matter rejection have been fully considered and are persuasive. The rejection of claims 1-4, 6-12,14-18, 21, 23-36, 38-48 and 50-54 has been withdrawn.

Claim Rejections - 35 USC § 112, 2nd Paragraph

Applicant's arguments, see p. 11, paragraph 7-8 and p. 12, paragraph 2 of remarks, filed 14 February 2007, with respect rejections under 35 USC 112, 2nd Paragraph have been fully considered and are persuasive. The rejection of claims 1 and 33 has been withdrawn.

Claim Rejections - 35 USC § 112

Applicant's arguments, see p. 12, paragraph 4-6 of remarks, filed 14 February 2007, with respect rejections under 35 USC 112, 1st Paragraph have been fully considered and are persuasive. The rejection of claims 15 and 30 has been withdrawn.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

1. Claims 1-4, 6, 9-11, 18, 21, 23, 28, 39 and 53 are rejected under 35 U.S.C. 102(e) as being anticipated by Taylor et al (PG PUB 2003/0082538).

Claim 1 is directed to a method for analyzing polymer intensity data from a sample comprising obtaining intensity profiles from individual labeled polymers contained in the sample, aligning individual intensity profiles from individual labeled polymers with respect to an alignment reference point, combining aligned individual intensity profiles to generate a population profile, selecting a peak in the population profile and obtaining individual intensity profiles that contribute to peak, combining individual intensity profiles that contribute to the peak to generate a peak profile, and comparing the peak profile with the population profile storing the intensity profile as a intensity vs. length profile. In some embodiments, the sample can contain a heterogeneous mixture of polymers that are of different sizes/lengths and the mixtures of polymers have different sequences. In some embodiments, the intensity is fluorescence and profiles are fluorescence profiles. In some embodiments, the polymers are embedded in a gel matrix. In another embodiment, the method is computer implemented. In some embodiments, the polymers are nucleic acids and specifically, DNA. In another embodiment, the intensity profiles are obtained from individual polymers in flow. In some embodiments, the sample profiles are average of the population of profiles and peak profiles are averages of profiles that make up a peak.

Taylor et al teach a method of analyzing polymer populations in which intensity profiles from individual labeled polymers are obtained ([0156]). The profiles are aligned with respect to an alignment reference point and combined to generate a sample population profile (fig. 16). Taylor shows selecting a peak in the sample profile and obtaining intensity profiles that contribute to the peak then combining the individual

intensity profiles to generate a peak profile and comparing the peak profile with the sample profiles (fig 18 vs. fig16). Taylor show the peak profile consists of a subset of peaks from the sample profile (compare figure 16 to figure 18) Storing intensity profiles as an intensity vs. length profile [0134 and 0156]. Taylor teaches that the sample can contain a heterogeneous mixture of polymers that are of different sizes/lengths [0134] and the mixtures of polymers have different sequences [0136]. Taylor teaches the sample is separated according to size prior the alignment [0134]. Taylor teaches that the intensity is fluorescence and profiles are fluorescence profiles [0156]. Taylor et al teaches the polymers are embedded in a gel matrix [0232]. Taylor teaches a computer-implemented method (abstract, line 1-2). Taylor teaches the polymer is the nucleic acid, DNA [0030]. Taylor teaches the intensity profiles are obtained from individual polymers in flow [0127]. Taylor et al show in figure 16, a sample profile that is an average of multiple profiles and in figure 17, a peak profile that is an average of multiple peak profiles.

2. Claims 1-4, 6-12, 14, 16-18, 21, 23-24, 26, 44-46, and 50-52 are rejected under 35 U.S.C. 102(b) as being anticipated by Chan (WO 98/35012).

The claims are directed to a method for analyzing polymer intensity data from a sample comprising obtaining intensity profiles from individual labeled polymers contained in the sample, aligning individual intensity profiles from individual labeled polymers with respect to an alignment reference point, combining aligned individual intensity profiles to generate a population profile, selecting a peak in the population

profile and obtaining individual intensity profiles that contribute to peak, combining individual intensity profiles that contribute to the peak to generate a peak profile, and comparing the peak profile with the population profile storing the intensity profile as a intensity vs. length profile. Further embodiments are drawn to the type of polymer, fluorescence data, labeling techniques, and data manipulations.

Chan teaches a method for analyzing polymer intensity data from a sample. To accomplish the analysis, Chan obtaining fluorescence intensity data from a collection of labeled nucleotide polymers (p. 18, line 25-28, p. 11, line 32-34). The polymers can be labeled at specific sites or labeled randomly (p. 18, line 31-32). The random labeling reads on the further embodiments of sequence nonspecific labels. Chan describes the use of reference points to align profiles from individual polymers (p. 63, lines 25-31). Chan teaches intensity data from labeled polymers (p. 23, line 17-22). Chan describes the method in which the signature of signals of a plurality of polymers, reading on the combined, aligned individual profiles that constitute a generated sample profile, are compared to a test profile, reading on a peak profile (p. 16, line 12-15 and p. 17, lines 2-7). Chan teaches intensity profiles stored as intensity vs. length profiles (p. 68, lines 7-15). In another embodiment, Chan teaches a method where the sample contains a heterogeneous mixture of polymers, differently sized fragments and with different sequences (p. 162, lines 8-9 and p. 74, lines 23-24). In another embodiment, Chan teaches a method where profiles are intensity versus length profiles and intensity is from fluorescence (p. 9, lines 9-13 and 33-35). In another embodiment, Chan teaches a method where the polymers are labeled with a sequence specific probe (p. 68, line 18 to

p.69 line 1). In another embodiment, Chan teaches a method where the method is implemented on a computer (p. 58, lines 29-32). In another embodiment, Chan teaches a method where the polymer is a nucleic acid that is DNA, and further genomic DNA (p. 8., lines 28-29). In another embodiment, Chan teaches a method where the reference point is an internal reference point and the reference point is a sequence specific probe (p.15, line 15-16). In another embodiment, Chan teaches a method where the polymers are in flow (col. 27, line 5-9). In another embodiment, Chan teaches a method where the population profile is an average population profile (p. 63, lines 18-24). In another embodiment, Chan teaches a method where polymers in the sample are sorted according to size prior to aligning individual intensity profiles (p. 119, line 35). In another embodiment, Chan teaches a method where the peak profile is an average peak profile (p. 40, line 31). In another embodiment, Chan teaches a method where peak is selected based on intensity (p. 40, lines 24-26). In another embodiment, Chan teaches a method where the polymer is completely stretched, partially stretched, or uniformly stretched (p. 101, lines 17-19). In another embodiment, Chan teaches a method where the peak is visible in an intensity vs. length profile (figs. 2 and 9). In another embodiment, Chan teaches a method where the peak corresponds to bin counts (p. 44, lines 6-7 and lines 11-12).

Allowable Subject Matter

The art does not fairly teach the concept of alignment of spectra based on an alignment reference point that is located centrally to the molecules being analyzed and the use of a mirror image spectra. As cited in the rejection above, alignment to the ends using an

end label is shown in the prior art. The art also does not to teach the generation of inverted or mirror profiles based on the central reference point.

Claims 25, 27, 29-36, 38, 40-43 and 54 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Karlheinz R. Skowronek whose telephone number is (571) 272-9047. The examiner can normally be reached on Mon-Fri 8:00am-5:00pm (EST).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla can be reached on (571) 272-0735. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Karlheinz R. Skowronek/

5/10/2007

10 May 2007

JOHN S. BRUSCA, PH.D
PRIMARY EXAMINER